

MCG7 (SEQ ID NOS: 4-5), and to a method of detecting a condition caused by an aberration in *mcg7* due to nucleotide alterations in the coding sequences.

### REMARKS

In the Office Action dated January 28, 2002, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-3, 8-10, 15-16, drawn to an isolated nucleic acid encoding a regulator of gene expression, MCG4 (SEQ ID NOS: 2-3), and to a method of detecting a condition caused by an aberration in *mcg4* due to nucleotide alterations in the coding sequence.
- II. Claims 1-2, 4-5, 8, 11-12, 15 and 19, drawn to an isolated nucleic acid encoding a regulator of gene expression. MCG7 (SEQ ID NOS: 4-5), and to a method of detecting a condition caused by an aberration in *mcg7* due to nucleotide alterations in the coding sequence.
- III. Claims 1-2, 4-5, 8, 11-12, 15 and 19, drawn to an isolated nucleic acid encoding a regulator of gene expression, MCG7 (SEQ ID NOS: 6-7), and to a method of detecting a condition caused by an aberration in *mcg7* due to nucleotide alterations in the coding sequence.
- IV. Claims 1-2, 6-8, 13-15 and 22, drawn to an isolated nucleic acid encoding a regulator of gene expression, MCG18 (SEQ ID NOS: 8-9), and to a method of detecting a condition caused by an aberration in *mcg18* due to nucleotide alterations in the coding sequence.
- V. Claim 17, drawn to a method of detecting a condition associated with an aberration in *mcg4* wherein a change in the amino acid sequence of MCG4 is detected (SEQ ID NO: 3).
- VI. Claim 18, drawn to a method of detecting MCG4 with an antibody directed against the protein (SEQ ID NO: 3).
- VII. Claim 20, drawn to a method of detecting a condition associated with an aberration in *mcg7* wherein a change in the amino acid sequence of MCG7 is

detected (SEQ ID NO: 5).

- VIII. Claim 21, drawn to a method of detecting MCG7 with an antibody directed against the protein (SEQ ID NO: 5).
- IX. Claim 20, drawn to a method of detecting a condition associated with an aberration in *mcg7* wherein a change in the amino acid sequence of MCG7 is detected (SEQ ID NO: 7).
- X. Claim 21, drawn to a method of detecting MCG7 with an antibody directed against the protein (SEQ ID NO: 7).
- XI. Claim 23, drawn to a method of detecting a condition associated with an aberration in *mcg18* wherein a change in the amino acid sequence of MCG18 is detected (SEQ ID NO: 9).
- XII. Claim 24, drawn to a method of detecting MCG18 with an antibody directed against the protein (SEQ ID NO: 9).

The Examiner alleges that the inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. More specifically, the Examiner alleges that the special technical feature of each group is the structural, functional characteristics of the specific nucleic acid or polypeptide featured in that group. For example, the special technical feature for each of Groups I-IV is based upon the particular nucleic acid sequence that encodes a specified regulator of gene expression. The special technical feature of each of Groups V, VII, IX and XI is based upon the particular amino acid sequence for a specified regulator of gene expression that is to be detected. The special technical feature for each of Groups VI, VIII, X and XII is based upon an antibody that specifically recognizes a given regulator of gene expression. Therefore, the Examiner requires Applicants to elect a single invention to which the claims must be restricted.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group II, Claims 1-2, 4-5, 8, 11-12, 15 and 19, drawn to an isolated nucleic acid molecule encoding a regulator of gene expression, MCG7 (SEQ ID NOS: 4-5), and to a method of detecting a condition caused by an aberration in mcg7 due to nucleotide alterations in the coding sequences. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

Applicants submit that Groups I-XII are not distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application. More specifically, the isolate nucleic acid molecules of Groups I-IV, i.e., MCG4, MCG7 and MCG18, all encode a protein having a regulatory role. Groups V, VII, IX and XI are drawn to methods of detecting a condition associated with an aberration in the isolated nucleic acid molecules of Groups I, II, II and IV, respectively, wherein a change in the amino acid sequence of the encoded protein is detected. Groups VI, VIII, X and XII are directed to methods of detecting the proteins encoded by the isolated nucleic acid molecules of Groups I, II, II and IV,

respectively, with an antibody directed against the protein. It is respectfully submitted that the isolated nucleic acid molecules of Groups I-IV, methods of detecting the protein product encoded by these nucleic acid molecules, and methods of detecting a change in the encoded protein product, are related to each other as different aspects of a single invention. It is submitted that each of the claimed inventions, when considered as a whole, defines a contribution over the prior art.

Accordingly, it is respectfully submitted that claims 1-24 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Frank S. DiGilio  
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343

FSD/XZ:ab